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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,616	09/05/2003	Felix Theeuwes	DURE-009	8016

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EXAMINER

HUH, BENJAMIN

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/656,616	Applicant(s) THEEUWES ET AL.	
	Examiner Benjamin Huh	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/5/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-32 and 49-62 is/are pending in the application.
 4a) Of the above claim(s) 24-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/5/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, mean-plus-function language to define Applicant's invention in claim 49 ... "a means for diverging the flow ...". Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) ...". (Also see MPEP 2181 (Rev. 1, Feb. 2000))

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 49-51, 53-54, 56-57, & 59-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Evans (US Patent No. 5466228). The Evans reference discloses a flow regulator for regulating flow of a drug to a treatment site within the body of a subject, the flow regulator in figures 1-2 comprising a drug reservoir see col. 3 lines 41-45, a delivery conduit (43,41) operably connected to the drug reservoir, a diversion conduit 20 operably connected either to the drug reservoir or to the delivery conduit through the diverting means 10, a means for diverting 10 the flow of drug from the delivery conduit to the diversion conduit, wherein the delivery conduit terminates at or near the treatment site, see col. 3 lines 30-46, and wherein the diversion conduit terminates at a site other than a treatment site and away from the treatment site, wherein the diversion conduit can be seen to be terminating into a waste container 30 in figure 1.

With regards to claim 50, wherein the diversion conduit would be fully capable of terminating at a site within the body of the subject other than the treatment site, due to it's size, shape, and ability to work in the environment.

With regards to claim 51, wherein the means for diverting the flow of drug comprises an adjustable valve, see col. 4 lines 12-52.

With regards to claim 53, wherein the flow regulator is fully capable of being fully implantable within the body of the subject, due to it's size, shape, and ability to work in the environment.

With regards to claim 54, wherein the valve comprises a rotatable valve, see col. 4 lines 12-52.

With regards to claim 56, wherein the delivery conduit and the diversion conduit intersect in a substantially T-shaped configuration, see figures 2A-2F in which the intersect is in a substantially T-shaped configuration.

With regards to claim 57, further comprising a waste reservoir 30 in fluid communication with the diversion conduit, see figure 1.

With regards to claim 59, wherein the delivery conduit comprises an attachment element, seen as the opposite end of the delivery conduit tubing which would be fully capable of attaching a drug delivery device for delivery of drug into the delivery conduit to due to it's size, shape, and ability to work in the environment.

With regards to claims 60-61, see col. 3 lines 30-39.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (US Patent No. 5466228) in view of Thompson (US Patent No. 4350155). Now even though the Evans reference does not explicitly disclose the remotely adjustable valve attention is directed to Thompson. The Thompson reference teaches a remotely adjusting valve in implanted systems with a power source, see col. 1 lines 35-38 & col. 3 lines 29-33. Therefore, it would have been obvious to one of ordinary skill in the art at

the time of the invention to use the teachings of Thompson in the regulator and system of Evans in order to obtain efficient control and access of the valve.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (US Patent No. 5466228) in view of Bouchard et al (US Patent No. 6416293). Now even though Evans does not explicitly disclose the use of a solenoid valve attention is directed to Bouchard. The Bouchard reference teaches the use of a solenoid valve, see col. 11 lines 55-62. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Evans to utilize the valve of Bouchard in order to provide an efficient and reliable valve.

Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (US Patent No. 5466228) in view of Savage et al (US Patent No. 5882602). Now even though Evans does not explicitly disclose the self-sealing septum in the waste reservoir attention is directed to Savage. The Savage reference teaches the use of a self-sealing septum, see col. 8 lines 40-52. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Savage in the regulator of Evans in order to provide access to the waste reservoir.

Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (US Patent No. 5466228) in view of Idriss (US Patent No. 4838887). Now even though Evans does not explicitly disclose the use of a programmable valve attention is

directed to Idriss. The Idriss reference teaches the use of programmable valves, see col. 4 lines 39-45. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Idriss in the regulator of Evans in order to achieve a higher level of control of the flow controlled by the valve.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sipin (US Patent No. 6280408B1) also discloses the use of solenoid valves.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BHH

KEVIN SIRMONS
PRIMARY EXAMINER

Kevin C. Sirmons